

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,255	03/09/2004	William A. Landi	2003P03684US01	2389
Siemens Corpo	7590 09/12/2007 ration	EXAMINER		
Intellectual Property Department			NGUYEN, MERILYN P	
170 Wood Ave Iselin, NJ 0883			ART UNIT	PAPER NUMBER
1301111, 143 00005	O .		2163	
			MAIL DATE	DELIVERY MODE
			09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		mn/			
	Application No.	Applicant(s)			
Office Action Cummons	10/796,255	LANDI ET AL.			
Office Action Summary	Examiner	Art Unit			
	Merilyn P. Nguyen	2163			
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet wit	h the correspondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNIC 36(a). In no event, however, may a re will apply and will expire SIX (6) MONT c, cause the application to become ABA	CATION. Sply be timely filed IHS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).			
Status .		·			
1) Responsive to communication(s) filed on 06/20	6/2007.				
	action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) ☐ Claim(s) 1-41 is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-41 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	wn from consideration.				
Application Papers	·				
9)☐ The specification is objected to by the Examiner.					
10)⊠ The drawing(s) filed on <u>10 March 2005</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.					
Applicant may not request that any objection to the					
Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureau * See the attached detailed Office action for a list	is have been received. is have been received in Aprity documents have been u (PCT Rule 17.2(a)).	pplication No received in this National Stage			
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview S	ummary (PTO-413)			
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	Paper No(s	s)/Mail Date Informal Patent Application			

Art Unit: 2163

DETAILED ACTION

1. In response to the communication dated 06/26/2007, claims 1-41 are pending in this action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 0106/26/2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 8, there is insufficient antecedent basis for "the step of automatically removing patient identifying information for a structured data record". Claim 8 depends on claim 6, which does not include the limitation of "the step of automatically removing patient identifying information for a structured data record".

Art Unit: 2163

Regarding claim 12, there is insufficient antecedent basis for "the step of removing the patient identifying information in the patient data record" (Emphasis added).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1, 3-7, 9-11, 15-21, 23-27, 29-31, and 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalies (US 2004/0143594), in view of Hagan (US 2001/0054155).

As per claims 1 and 21, Kalies teaches "obtaining a patient data record of a patient which includes patient identifying information; removing the patient identifying information in the patient data record to generate a de-identified data record" (see Abstract and paragraphs [0035-0036]). Kalies teaches encrypt/decrypt feature as the de-identified patient information is encrypted and then transmitted to user. The de-identified patient information is then decrypted and made available for the user to view. However, Kalies is silent as to "generating an encrypted ID for the patient, wherein the encrypted ID comprises an encrypted representation of one or more items of patient identifying information; and storing the encrypted ID with or in the de-identified data record". On the other hand, Hagan teaches generating an encrypted ID for the patient, wherein the

Art Unit: 2163

encrypted ID comprises an encrypted representation of one or more items of patient identifying information; and storing the encrypted ID with or in the de-identified data record (see Figure 3 and paragraph [0029] and [0069] and [0110]). It would have been obvious to one having ordinary skill in the art at the time of the invention was made to generate an encrypted ID for the patient such as UAI and to store the de-identified data record in the database indexed by UAI as suggested by Hagan. The motivation would have been to ensure the confidentiality, privacy and security of users' personal records or patient information (paragraphs [0029] and [0063], Hagan et al.).

As per claims 3, 5, 23 and 25, Kalies/Hagan teaches "securely maintaining a decryption key, which can be accessed by an authorized entity to decrypt the encrypted ID in the de- identified data record to re-identify the patient" (see paragraph [0099], Hagan et al.).

As per claims 4 and 24, Kalies/Hagan teaches wherein the decryption key is a private key that is associated with the public key for encryption (see paragraph [0081], Hagan et al.).

As per claims 6 and 26, Kalies/Hagan teaches "wherein the step of removing the patient identifying information in the patient data record to generate a de-identified data record is performed in compliance with a Safe Harbor rule or Limited Data set Rule of HIPAA" (see paragraph [0015], Kalies et al.).

Art Unit: 2163

As per claims 7, 9, 27 and 29, Kalies/Hagan teaches wherein the step of removing the patient identifying information in the patient data record includes automatically removing patient identifying information from a structured/unstructured data record (See paragraph [0036], Kalies et al.).

As per claims 10 and 30, Kalies/Hagan teaches wherein the steps of automatically removing patient identifying information from an unstructured data records comprises locating a text string in the unstructured data records that includes patient identifying information, and removing the text string from the unstructured data record (See paragraph [0036], Kalies et al.).

As per claims 11 and 31, Kalies/Hagan teaches "wherein the text string to be removed from the unstructured data record is determined based on a matching text string that is included in a database element of a structured data record associated with the unstructured data record" (see paragraph [0036], Kalies et al.).

As per claims 15 and 34, Kalies/Hagan teaches "mapping the encrypted ID to a Study ID that comprises an arbitrary human readable ID which contains no patient identifying information; and generating a data structure that includes the mapping" (see paragraph [0116], Hagan et al.).

Art Unit: 2163

As per claims 16 and 35, Kalies/Hagan teaches "mapping the Study ID to one or more replacement strings that can be used to replace de-identified data in the de-identified data record (see paragraph [0116], Hagan et al.)

As per claim 17, Kalies/Hagan teaches making the data structure publicly accessible (See paragraph [0116], Hagan et al.)

As per claim 18, Kalies/Hagan teaches using the encrypted ID or corresponding Study ID to recognize a subject patient of patient data records collected at different times (See paragraph [0027], Hagan et al.)

As per claim 19, Kalies/Hagan teaches "wherein the method is implemented for sharing patient data for purposes of research" (see paragraph [0020], Kalies et al.).

As per claim 20, Kalies/Hagan teaches "wherein the method is implemented for sharing patient data for purposes of central monitoring for natural or human induced disease outbreaks" (see paragraph [0020], Kalies et al.).

As per claim 36-39, these claims are rejected on grounds corresponding to the arguments given above for rejected claim 1, 3 and are similarly.

As per claims 40-41, the claims are rejected on grounds corresponding to the arguments given above for rejected claims 1-5 and is similarly rejected.

Art Unit: 2163

5. Claims 2 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalies (US 2004/0143594), in view of Hagan (US 2001/0054155) and further in view of Nagel (US 7,181,017).

As per claims 2 and 22, Kalies/Hagan disclose all the claimed subject matter as set forth above; Kalies/Hagan further discloses the UAI is encrypted under a key (See paragraph [0029], Hagan et al.); however, Kalies/Hagan is silent as to encrypting the one or more items of patient identifying information using a public key. On the other hand, Nagel teaches encrypting patient identifying information using a public key (see col. 22, line 64 to col. 24 line 24, Nagel et al.). It would have been obvious to one having ordinary skill in the art at the time of the invention was made to encrypting patient identifying information using a public key as suggested by Nagel. The motivation would have been to allow an additional or substitute layer of security to sensitive patient identifying information (See col. 22, lines 66-67).

6. Claims 12-14 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalies (US 2004/0143594), in view of Hagan (US 2001/0054155) and further in view of Jordan (US 6,823,203).

As per claims 12 and 32, Kalies/Hagan disclose all the claimed subject matter as set forth above; Kalies/Hagan further discloses removing photographs and images (See paragraph [0036], Kalies et al.); however, Kalies/Hagan is silent as to disclose automatically removing patient information from an image. On the other hand, Jordan teaches automatically removing patient information from an image (See Figures 6 and 7

Art Unit: 2163

and col. 8, line 61 to col. 9, line 61, Jordan et al.). It would have been obvious to one having ordinary skill in the art at the time of the invention was made to automatically removing patient information from an image as suggested by Jordan. The motivation would have been to protect patient confidentiality and to remove only patient specific identifiers from images so that to enable the exported images to be used for educational purposes and public presentations (See col. 1, lines 58-63, Jordan et al.).

As per claims 13 and 33, Kalies/Hagan/Jordan discloses removing patient identifier information contained in structured fields (See Figures 6B-6D, Jordan et al.).

As per claim 14, Kalies/Hagan/Jordan discloses "manually identifying burned-in patient identifying information within an image and automatically blanking the identified patient identifying information" (see Figures 6C-6D, Jordan et al.).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dick U.S 2002/0116227 discloses method and apparatus for requesting, retrieving, and obtaining de-identified medical information.

Iverson US Patent No. 7,158,979 discloses system and method of de-identifying data.

8. Any inquiry concerning this communication or earlier communications from the

Art Unit: 2163

examiner should be directed to Merilyn P Nguyen whose telephone number is 571-272-4026.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Don Wong can be reached on 571-272-1834. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-746-7240 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3900.

MN

September 04, 2007

WILSON LEE
PRUMARY EXAMINER